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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Declaration that Circumstances Exist Justifying Authorization of Emergency Use of All Oral Formulations of Doxycycline Accompanied by Emergency Use Information

AGENCY: Office of the Secretary (OS), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Secretary of Homeland Security determined on September 23, 2008, that there is a significant potential for a domestic emergency involving a heightened risk of attack with a specified biological, chemical, radiological, or nuclear agent or agents—in this case, *Bacillus anthracis*—pursuant to section 564(b)(1)(A) of the Federal Food, Drug, and Cosmetic (FD&C) Act.¹ On the basis of that determination, and pursuant to section 564(b) of the FD&C Act, the Secretary of Health and Human Services (HHS) is declaring that circumstances exist

¹ Section 564 of the FD&C Act is codified at 21 U.S.C. § 360bbb-3.

justifying the authorization of emergency use of all oral formulations of doxycycline accompanied by emergency use information subject to the terms of any authorization issued by the Commissioner of Food and Drugs under section 564(a) of the FD&C Act. This notice is being issued in accordance with section 564(b)(4) of the FD&C Act.

DATES: This Notice and referenced HHS declaration are effective as of June 27, 2013.

FOR FURTHER INFORMATION CONTACT: Nicole Lurie, MD, MSPH, Assistant Secretary for Preparedness and Response, Office of the Secretary, Department of Health and Human Services, 200 Independence Avenue SW, Washington, DC 20201, Telephone (202) 205–2882 (this is not a toll free number).

SUPPLEMENTARY INFORMATION:

I. Background

On September 23, 2008, former Secretary of Homeland Security, Michael Chertoff, determined, pursuant to section 564(b)(1)(A) of the FD&C Act, that there is a significant potential for a domestic emergency involving a heightened risk of attack with a specified biological, chemical, radiological, or nuclear agent or agents—in this case, *Bacillus anthracis*—although there is no current domestic emergency involving anthrax, no current heightened risk of an anthrax attack, and no credible information indicating an imminent threat of an attack involving *Bacillus anthracis*. On October 1, 2008, on the basis of that determination, and pursuant to section 564(b)

of the FD&C Act, former HHS Secretary, Michael O. Leavitt, declared an emergency justifying the emergency use of doxycycline hyclate tablets accompanied by emergency use information subject to the terms of any authorization issued under section 564(a) of the FD&C Act.² On October 1, 2009 and October 1, 2010, I renewed the former Secretary's declaration,³ and on July 20, 2011, I renewed and amended the declaration to declare that the emergency justifies emergency use of all oral formulations of doxycycline accompanied by emergency use information subject to the terms of any authorization issued under section 564(a) of the FD&C Act.⁴ On June 28, 2012, I renewed my July 20, 2011 declaration.⁵

II. Declaration of the Secretary of Health and Human Services

On the basis of the September 23, 2008 determination by the Secretary of Homeland Security and pursuant to section 564(b) of the FD&C Act, I hereby declare that circumstances exist justifying the authorization of emergency use of all oral formulations of doxycycline accompanied by emergency use information subject to the terms of any authorization issued

² Pursuant to section 564(b)(4) of the FD&C Act, notice of the determination by the Secretary of Homeland Security and the declaration by the HHS Secretary was provided at 73 FR 58242 (October 6, 2008).

³ Pursuant to section 564(b)(4) of the FD&C Act, notices of the renewals of the declaration of the HHS Secretary were provided at 74 FR 51,279 (Oct. 6, 2009) and 75 FR 61,489 (Oct. 5, 2010).

⁴ Pursuant to section 564(b)(4) of the FD&C Act, notice of the renewal and amendment of the declaration of the HHS Secretary was provided at 76 FR 44,926 (July 27, 2011).

⁵ Pursuant to section 564(b)(4) of the FD&C Act, notice of the renewal of the declaration of the HHS Secretary was provided at 77 FR 39,708 (July 5, 2012).

under section 564(a) of the FD&C Act.⁶ I am issuing this notice in accordance with section 564(b)(4) of the FD&C Act.

June 27, 2013

Dated

Kathleen Sebelius

Secretary

⁶ Section 564(b)(1) of the FD&C Act was amended by section 302 of the Pandemic and All-Hazards Preparedness Reauthorization Act, Pub. L. No. 113-5, to provide that the HHS Secretary may “make a declaration that the circumstances exist justifying the authorization” for a product. under section 564 of the FD&C Act on the basis of one of four determinations specified under subsection 564(b)(1) of the FD&C Act, including a determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a, chemical, biological, radiological, or nuclear agent or agents.